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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/209,023 12/10/98 PATON

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EXAMINER

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HUNT, J

ART UNIT

PAPER NUMBER

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1642

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/209,023

Applicant(s)

Paton et al.

Examiner
Jennifer Nichols, Nee Hunt

Group Art Unit
1642



- ☐ Responsive to communication(s) filed on _____
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-33 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-33 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☒ Notice of References Cited, PTO-892
- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 4,5
- ☐ Interview Summary, PTO-413
- ☒ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Double Patenting

1. Claims 1-19 of this application conflict with claims 1-19 of Application No. 09/208,649. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

2. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

3. Claims 1-19 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-19 of copending Application No. 09/208,649. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-19 are unclear in the recitation of “susceptible to a disorder characterized by over expression of ErbB2 receptor” or “...a condition characterized by...”. The metes and bounds of susceptible to cannot be determined from the claims as recited. No characteristics or defining qualities of “susceptible to” are set forth and therefor it is not possible to determine what properties “susceptible to” encompasses. Further, it is not clear what properties and level of symptoms are definitive of a “disorder or condition characterized by...”. The claims and specification sets forth some of the embodiments included but fail to set forth bounds of what is included or guidance to define said disorders and conditions.

Claims 1-13 and 20-31 are unclear in the recitation of an “effective amount” or “efficacy”. The metes and bounds of an effective amount or efficacy cannot be determined from the claims as recited. It is unclear what is being effected and therefor it is not possible to determine what amount would be effective, and it is unclear what the desired outcome or endpoint is from the claims as recited.

Claims 15 and 16 are unclear in the recitation of a label on or associated with the container. It is not clear how a label can associate with a container.

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Claim 17 recites the limitation "the receptor". There is insufficient antecedent basis for this limitation in the claim.

Claims 20-29 and 30-33 are unclear in the recitation of a cardioprotectant. The metes and bounds of a cardioprotectant cannot be determined. A precise definition of cardioprotectant is never set forth and it is not possible to determine what compositions would be considered a cardioprotectant and what would not.

Claim 22 is unclear because it contains an improper markush group. The proper format for a Markush Groups is "...selected from the group consisting of....and...".

Claim 24 is unclear because it contains an improper markush group. One suggestion to overcome this rejection would be to change "...hepatic carcinoma, head and neck cancer" to "...hepatic carcinoma, and head and neck cancer".

Claim 27 is unclear in the recitation of "administered with...". It is not clear if the cardioprotectant and antibody must be administered together, or if they can be administered singularly. Further it is not clear if "with" refers to administration at the same time, or administration at all.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

7. Claims 1-13 are rejected under 35 U.S.C. 102(a) as being anticipated by Baselga et al.,
Oncology, Vol 11, No 3, March 1997.

Baselga et al teaches a method of treatment of a human patient diagnosed with a disorder characterized by over expression of ErbB2 receptor, specifically metastatic breast cancer, comprising administering and effective amount of an anti-ErbB2 antibody which binds the 4D5 epitope in the HER2 extracellular domain, and a chemotherapeutic agent other than an anthracycline derivative, in the absence of an anthracycline derivative to a human patient. The chemotherapeutic agent paclitaxel is used.(page 46 - page 47, column 1) The effective amount of the combination is less than the sum of the effective amounts of the chemotherapeutic agent and antibody individually (page 46, columns 1 and 3) The efficacy of this method is measured by time to disease progression (page 47, column 1).

8. Claims 1-11 are rejected under 35 U.S.C. 102(a) as being anticipated by Norton,
Seminars in Oncology, Vol 24, No 4, Suppl 10, August 1997.

Norton teaches a method of treatment of a human patient diagnosed with a disorder characterized by over expression of ErbB2 receptor, specifically metastatic breast cancer, comprising administering and effective amount of an anti-ErbB2 antibody which binds the 4D5 epitope in the HER2 extracellular domain, and a chemotherapeutic agent other than an anthracycline derivative, in the absence of an anthracycline derivative to a human patient. The

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chemotherapeutic agent paclitaxel is used. (See pages S10 8- S109, in the Patient Selection section and Table 1)

9. Claims 1-5, 7-9, and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Lippman et al, US Patent 5,578,482, November 26, 1996.

Lippman et al. teaches a method of treatment of a human patient diagnosed with a disorder characterized by over expression of ErbB2 receptor, specifically breast, lung, ovarian, thyroid, salivary gland or prostate cancer, comprising administering and effective amount of an anti-ErbB2 antibody which binds the 4D5 epitope in the extracellular domain, and a chemotherapeutic agent. Lippman et al. further teaches various doses as effective amounts. Lippman et al. further teaches co-administration of "any chemotherapeutic" which would include non-anthracycline agents.(columns 9 and 26-29)

10. Claims 1-5, 7-9, and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Hynes et al. Biochemica et Biophysica Acta 1198, 1994.

Hynes et al. teaches a method of treatment of a human patient diagnosed with a disorder characterized by over expression of ErbB2 receptor, specifically breast cancer, comprising administering and effective amount of an anti-ErbB2 antibody which binds the 4D5 extracellular domain, and a chemotherapeutic agent, cisplatin, which is not an anthracycline derivative. Further, Hynes teaches that the Antibody acts synergistically therefor the effective amount of the combination of antibody and chemotherapeutic agent is less than the sum of the effective

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amounts of the antibody and the chemotherapeutic agent individually. (page 178, column2, paragraph 1).

11. Claims 1-5 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Arakawa et al, US Patent 5,783,186.

Arakawa et al. Teaches a method of treating human breast cancer which comprises administering an anti-ErbB2 antibody and a non-anthracycline chemotherapeutic agent, wherein coadministration enhances the therapeutic effect so that the effective amount is less than the effective amount of the antibody or chemotherapeutic agent when administered individually.

(Column 5, line 66-column 6, line 29)

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hudziak et al., US Patent 5,770,195.

Hudziak et al. teaches a method of treatment of any mammal diagnosed with a disorder characterized by over expression of ErbB2 receptor, specifically breast cancer, comprising administering and effective amount of an anti-ErbB2 antibody which binds the extracellular

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domain, and a chemotherapeutic agent which is not an anthracycline derivative. Hudziak fails to teach administration to humans.

Although Hudziak et al. is silent with respect to the administration of the therapy to human patients, humans would be encompassed by the scope of mammals and the therapy is clearly intended for human use, as the antibody binds a human cell receptor.

Therefor it would have been *prima facie* obvious to one of ordinary skill in the art to administer the therapy taught in Hudziak et al. to human patients, and one would have been motivated to do so because all receptors and cytotoxic factors are specific human factors and the treatment was ultimately intended for human use, as taught by Hudziak et al in the background of invention.

14. Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baselga et al, Journal of Clinical Oncology, Vol 14, No 3, March 1996, in view of Hynes et al, Biochimica et Biophysica Acta, 1994, page 178.

Baselga et al in Journal of Clinical Oncology teaches a method of treatment of a human patient diagnosed with a disorder characterized by over expression of ErbB2 receptor, specifically metastatic breast cancer, comprising administering an effective amount of an anti-ErbB2 antibody which binds the 4D5 extracellular domain (page 737, last paragraph). Time to response rate was used to measure efficacy (page 738, last paragraph). Although Baselga et al. fails to teach the administration of the antibody in combination with a chemotherapeutic to

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humans, it does teach that the antitumor effects of paclitaxel are potentiated by coadministration with the antibody and that this method is currently being administered to humans in clinical trials (page 743, last paragraph). Baselga et al further fails to teach that the effective amount of the chemotherapeutic agent and the antibody are less than the effective amounts of those compounds administered individually.

Hynes et al teaches that coadministration of an anti-ErbB2 antibody and a non-anthracycline derivative chemotherapeutic agent produces a synergistic treatment effect. Therefor the effective amount of the chemotherapeutic agent and the antibody are less than the effective amounts of those compounds administered individually.

Therefor it would have been *prima facie* obvious to one of ordinary skill in the art to administer the method of Baselga et al to human patients with a reasonable expectation of success and one would have been motivated to do so because administration of antibody is an effective method of treating metastatic breast cancer and coadministration of antibody and paclitaxel enhanced anti-tumor effects, as taught by Baselga et al. Further, coadministration of antibody and chemotherapeutic agent produces a synergistic therapeutic response, as taught by Hynes et al. Further, "it is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose in order to form the third composition that is to be used for the very same purpose: idea of combining them flows logically from their having been taught individually in the prior art." In re Kerkhoven (205 USPQ 1069, CCPA 1980). It is well known in the art as set forth above that anti-Her2 antibodies and the

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chemotherapeutic paclitaxel are both useful for inhibiting the growth of tumors. Methods of inhibiting tumor growth by using chemotherapy are well established and therefore it would be obvious to use chemotherapy treatment in combination with an antibody therapy which has been established to be effective.

15. Claims 1-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baselga et al., Journal of Clinical Oncology, Vol 14, No 3, March 1996, in view of Singal et al., Journal of Molecular Cell Cardiology, Vol 27, 1995, and further in view of Seifert et al., The Annals of Pharmacology, Vol 28, September 1998.

Baselga et al teaches as applied to claims 1-13 supra. Baselga fails to teach the corresponding articles of manufacture, including a warning not to administer the HER2 antibody with anthracycline derivatives and anthracycline-type chemotherapeutics, or when they are administered to administer with a cardioprotectant.

Articles of manufacture which comprise the reagents necessary to administer a particular treatment are well known in the art. Further, Singal et al. teaches that anthracycline derivatives are known to cause severe heart failure, thereby making anthracycline derivatives less desirable than other chemotherapeutics. Singal further teaches that administration with a cardioprotectant, including probucol alleviates the risks of anthracycline administration (see abstract). Singal fails to teach the cardioprotectant dexrazoxane.

Seifert et al. teaches that the cardioprotectant dexrazoxane is useful as a cardioprotectant to alleviate the dangers of anthracycline therapy.(page 1063, conclusions)

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Therefor it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to package the reagents necessary for the method taught by Baselga et al. into a convenient kit form for the purposes of increased marketability convenience, reliability, and economy. Further it would be *prima facie* obvious to include a warning to avoid use of an anthracycline derivative, as these chemotherapeutics are known to cause fatal heart problems in some patients, or when they are administered to administer with a cardioprotectant. as taught by Singal et al. and Seifert et al.

16. Claims 1-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baselga et al., Oncology, Vol 11, No 3, March 1997, in view of Singal et al., Journal of Molecular Cell Cardiology, Vol 27, 1995, and further in view of Seifert et al., The Annals of Pharmacology, Vol 28, September 1998.

Baselga et al teaches as applied to claims 1-13 supra. Baselga fails to teach the corresponding articles of manufacture, including a warning not to administer the HER2 antibody with anthracycline derivatives and anthracycline-type chemotherapeutics, or when they are administered to administer with a cardioprotectant.

Articles of manufacture which comprise the reagents necessary to administer a particular treatment are well known in the art. Further, Singal et al. teaches that anthracycline derivatives are known to cause severe heart failure, thereby making anthracycline derivatives less desirable than other chemotherapeutics. Singal further teaches that administration with a cardioprotectant,

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including probucol alleviates the risks of anthracycline administration (see abstract). Singal fails to teach the cardioprotectant dexrazoxane.

Seifert et al. teaches that the cardioprotectant dexrazoxane is useful as a cardioprotectant to alleviate the dangers of anthracycline therapy.(page 1063, conclusions)

Therefor it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to package the reagents necessary for the method taught by Baselga et al. into a convenient kit form for the purposes of increased marketability convenience, reliability, and economy. Further it would be *prima facie* obvious to include a warning to avoid use of an anthracycline derivative, as these chemotherapeutics are known to cause fatal heart problems in some patients, or when they are administered to administer with a cardioprotectant. as taught by Singal et al. and Seifert et al.

17. Claims 1-11 and 14-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Norton, Seminars in Oncology, Vol 24, No 4, Suppl 10, August 1997, in view of Singal at al., Journal of Molecular Cell Cardiology, Vol 27, 1995, and further in view of Seifert et al., The Annals of Pharmacology, Vol 28, September 1998.

Norton teaches as applied to claims 1-11 supra. Norton fails to teach the corresponding articles of manufacture, including a warning not to administer the HER2 antibody with anthracycline derivatives and anthracycline-type chemotherapeutics, or when they are administered to administer with a cardioprotectant.

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Articles of manufacture which comprise the reagents necessary to administer a particular treatment are well known in the art. Further, Singal et al. teaches that anthracycline derivatives are known to cause severe heart failure, thereby making anthracycline derivatives less desirable than other chemotherapeutics. Singal further teaches that administration with a cardioprotectant, including probucol alleviates the risks of anthracycline administration (see abstract). Singal fails to teach the cardioprotectant dexrazoxane.

Seifert et al. teaches that the cardioprotectant dexrazoxane is useful as a cardioprotectant to alleviate the dangers of anthracycline therapy.(page 1063, conclusions)

Therefor it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to package the reagents necessary for the method taught by Norton into a convenient kit form for the purposes of increased marketability convenience, reliability, and economy. Further it would be *prima facie* obvious to include a warning to avoid use of an anthracycline derivative, as these chemotherapeutics are known to cause fatal heart problems in some patients, or when they are administered to administer with a cardioprotectant. as taught by Singal et al. and Seifert et al.

18. Claims 1-5, 7-9, 12, and 14-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lippman et al, US Patent 5,578,482, November 26, 1996, in view of Singal et al., Journal of Molecular Cell Cardiology, Vol 27, 1995, and further in view of Seifert et al., The Annals of Pharmacology, Vol 28, September 1998.

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Lippman et al. teaches as applied to claims 1-5, 7-9 and 12 supra. Lippman et al. fails to teach the corresponding articles of manufacture, including a warning not to administer the HER2 antibody with anthracycline derivatives and anthracycline-type chemotherapeutics, or when they are administered to administer with a cardioprotectant.

Articles of manufacture which comprise the reagents necessary to administer a particular treatment are well known in the art. Further, Singal et al. teaches that anthracycline derivatives are known to cause severe heart failure, thereby making anthracycline derivatives less desirable than other chemotherapeutics. Singal further teaches that administration with a cardioprotectant, including probucol alleviates the risks of anthracycline administration (see abstract). Singal fails to teach the cardioprotectant dexrazoxane.

Seifert et al. teaches that the cardioprotectant dexrazoxane is useful as a cardioprotectant to alleviate the dangers of anthracycline therapy.(page 1063, conclusions)

Therefor it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to package the reagents necessary for the method taught by Lippman et al. into a convenient kit form for the purposes of increased marketability convenience, reliability, and economy. Further it would be *prima facie* obvious to include a warning to avoid use of an anthracycline derivative, as these chemotherapeutics are known to cause fatal heart problems in some patients, or when they are administered to administer with a cardioprotectant. as taught by Singal et al. and Seifert et al.

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19. Claims 1-5, 7-9, 12, and 14-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hynes et al. Biochemica et Biophysica Acta 1198, 1994, in view of Singal et al., Journal of Molecular Cell Cardiology, Vol 27, 1995, and further in view of Seifert et al., The Annals of Pharmacology, Vol 28, September 1998.

Hynes et al. teaches as applied to claims 1-5, 7-9, and 12 supra. Hynes et al. fails to teach the corresponding articles of manufacture, including a warning not to administer the HER2 antibody with anthracycline derivatives and anthracycline-type chemotherapeutics, or when they are administered to administer with a cardioprotectant.

Articles of manufacture which comprise the reagents necessary to administer a particular treatment are well known in the art. Further, Singal et al. teaches that anthracycline derivatives are known to cause severe heart failure, thereby making anthracycline derivatives less desirable than other chemotherapeutics. Singal further teaches that administration with a cardioprotectant, including probucol alleviates the risks of anthracycline administration (see abstract). Singal fails to teach the cardioprotectant dexrazoxane.

Seifert et al. teaches that the cardioprotectant dexrazoxane is useful as a cardioprotectant to alleviate the dangers of anthracycline therapy.(page 1063, conclusions)

Therefor it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to package the reagents necessary for the method taught by Hynes et al. into a convenient kit form for the purposes of increased marketability convenience, reliability, and economy. Further it would be *prima facie* obvious to include a warning to avoid use of an

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anthracycline derivative, as these chemotherapeutics are known to cause fatal heart problems in some patients, or when they are administered to administer with a cardioprotectant. as taught by Singal et al. and Seifert et al.

20. Claims 1-5, 12, and 14-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arakawa et al, US Patent 5,783,186, in view of Singal et al., Journal of Molecular Cell Cardiology, Vol 27, 1995, and further in view of Seifert et al., The Annals of Pharmacology, Vol 28, September 1998.

Arakawa et al. teaches as applied to claims 1-5 and 12 supra. Arakawa et al. fails to teach the corresponding articles of manufacture, including a warning not to administer the HER2 antibody with anthracycline derivatives and anthracycline-type chemotherapeutics, or when they are administered to administer with a cardioprotectant.

Articles of manufacture which comprise the reagents necessary to administer a particular treatment are well known in the art. Further, Singal et al. teaches that anthracycline derivatives are known to cause severe heart failure, thereby making anthracycline derivatives less desirable than other chemotherapeutics. Singal further teaches that administration with a cardioprotectant, including probucol alleviates the risks of anthracycline administration (see abstract). Singal fails to teach the cardioprotectant dexrazoxane.

Seifert et al. teaches that the cardioprotectant dexrazoxane is useful as a cardioprotectant to alleviate the dangers of anthracycline therapy.(page 1063, conclusions)

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Therefor it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to package the reagents necessary for the method taught by Arakawa et al. into a convenient kit form for the purposes of increased marketability convenience, reliability, and economy. Further it would be *prima facie* obvious to include a warning to avoid use of an anthracycline derivative, as these chemotherapeutics are known to cause fatal heart problems in some patients, or when they are administered to administer with a cardioprotectant. as taught by Singal et al. and Seifert et al.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Hunt whose telephone number is (703) 308-7548. The examiner can normally be reached Monday through Thursday 6:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell can be reached at (703) 308-4310. The fax number for the group is (703) 305-3014 or (703) 308-4242.

Communications via internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [paulahutzell@uspto.gov].

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All internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists the possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist, whose telephone number is (703) 308-0196.

Jennifer Hunt

December 29, 1999


YVONNE EYLER, PH.D
PRIMARY EXAMINER